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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,643	12/22/2000	Todd M. Boyce	285-113 CON	1535

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,643

Applicant(s)

BOYCE ET AL

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4,5,8,9, 21,24 are rejected under 35 U.S.C. 102(e) as being anticipated by Marino (6290724). Marino shows (Fig. 1A) a "substantially" cylindrical body with at least two tabs **36** longitudinally placed from the two ends of the vertebral implant. The use of "substantially cylindrical body" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be seen that the tabs are radially spaced that a first tab is approximately 180° from a second tab on the opposite side. It can also be seen that there is a throughbore **42** which is perpendicular to the longitudinal axis and radially spaced from the tabs. The tabs have a width less than or *equal* to the maximum diameter of the body. Marino discloses the implant is formed from bone or material derived from bone, col. 6, lines 31-42. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Thus the tabs are fully capable of "possessing a configuration and dimensions of preformed recesses."

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4-7,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godefroy et al. (5683463) in view of Bianchi et al. (6033438). Fig. 6 shows a "substantially" cylindrical body having at least two tabs **16, 14** radially spaced approximately 180° about the body of the implant and have a width at least less than or *equal* to the maximum diameter of the body. It can also be seen there is at least one throughbore **9**. Fig. 1 shows a body portion with one end having an installation slot **24** and a bore **23** between the slot. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Thus the tabs are fully capable of "possessing a configuration and dimensions of preformed recesses." However, Godefroy et al. do not disclose the use of bone for the implant. Bianchi et al. teach the advantages of using bone as an implant, i.e., it allows excellent postoperative imaging, col. 2, lines 13-26. Bianchi also teaches that intervertebral implants are made from the bone, col. 5, lines 40-58. Bianchi additionally teaches that bone implants with surface features aid in stabilization and facilitate fusion, col. 8, lines 11,12. It would have been obvious to one of ordinary skill in the art to use bone as taught by Bianchi et al. for the implant of Godefroy et al. in order to provide a preserved biological material that is fully capable of being stabilized in the vertebrae while also facilitating fusion.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Scarborough (5676146). Marino is explained supra. However, Marino does not disclose the use of animal bone for the implant. Scarborough teaches to use animal bone for an implant, col. 2, lines 13-15 and for vertebral repair, col. 3, lines 11-22. It would have been obvious to one of ordinary skill in the art to use animal bone as

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taught by Scarborough in the implant of Marino in order to provide a radiolucent material for easier tracking the implant after implantation.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Lewandrowski et al. (J. Biomat. Res.). Marino is explained supra. However, Marino does not disclose the surface is demineralized. Lewandrowski et al. teach that demineralization enhances bone osteoinductive properties, p.365. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Lewandrowski et al. in the implant of Marino in order to provide a prosthesis capable of stabilizing the vertebrae while stimulate bone ingrowth.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Kuslich et al. (5445639). Marino is explained supra. Marino discloses forming a core and the implant is positioned by rotating, col. 14, lines 12-26. Marino also discloses implants and the vertebral space that the implant engages are often matched with respect to one another, col. 4, lines 10-24. However, Marino does not disclose the step of forming a stepped bore in a portion of the vertebrae. Kuslich et al. teach to bore areas for vertebral implants with progressively increased blades that can be interpreted to be a stepped bore form, col. 7, lines 55-66. Fig. 17 shows an enlarged chamber or stepped bore. Kuslich also teaches the stepped bore or cavity formed for the implant is designed such that the implant is secured in place, col. 4, lines 56,57. It would have been obvious to one of ordinary skill in the art to use the method of boring vertebrae in a stepped fashion such that the cavity formed accommodates the structure of the implant as taught by Kuslich et al. for inserting the implant of Marino with tabs in

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the implanting procedure. As a result, the enlarged area for the implant with tabs is ready to receive the device and not require any forceful rotation or positioning causing trauma to the patient.

Response to Arguments

Applicant's arguments filed 6/2/03 have been fully considered but they are not persuasive. With respect to the remarks that the Marino implant is not "substantially" cylindrical, it must be noted that MPEP 2173.05(b) states that "substantially" is a broad term. Therefore, it is proper to interpret the limitations "substantially cylindrical" with structure that has some sort of deviation from being cylindrical. Also note that at one end **22** of the Marino implant, it is clearly cylindrical. Regarding the comments that the tabs correspond to preformed recesses and that Marino's tabs do not, cannot serve to distinguish apparatus claims because claim 1 is not a method of implanting or step of forming any recesses in vertebrae. Additionally the claim fails to even state any dimensions as to the preformed recesses other than they correspond to some undefined structure called tabs. Therefore, if the surgeon desires, they could form preformed recesses to correspond to the tabs. Again to reiterate, since this is a product claim, the method of using the device (with preformed recesses) is irrelevant to patentability of the product itself.

Regarding the Godefroy/Bianchi rejection, it must be noted that the tabs of the Godefroy implant as modified by Bianchi are fully capable of possessing a configuration and a dimension to complement a preformed recess within the vertebrae. As

mentioned above, since the claims are directed to a product, the method of using the device (with preformed recesses) is irrelevant to patentability of the product itself.

With respect to method claim 23, Kuslich teaches that forming a stepped bore accommodates an implant structure to snugly fit therein. By forming a stepped bore, the implant of Marino clearly can be seated within the stepped bore and fitting within the enlarged diameter. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the tabs being seated within the stepped bore *causes locking the implant in place and inhibits its axial or rotational displacement*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



BRUCE SNOW
PRIMARY EXAMINER

Brian E. Pellegrino
August 21, 2003
TC 3700, AU 3738

